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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB14

National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of public hearing.

SUMMARY: This document announces a public hearing to receive information and comments regarding the notice of proposed rulemaking (NPRM) titled “National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table.”

DATE AND TIME: September 17, 2018, from 10:00 a.m. to 11:30 a.m. ET.

LOCATION: 5600 Fishers Lane, Conference Room 08SWH01, Rockville, MD 20857 (and via audio conference call and Adobe Connect).

The public can join the hearing by:

1. (In Person) The hearing will take place at 5600 Fishers Lane, Rockville, MD 20857.

Persons interested in attending the hearing in person are encouraged to submit a written notification to: Ana Marie Balingit-Wines, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 08N146B, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: abalingit-wines@hrsa.gov. Since this hearing is held in a Federal government building, attendees must go through a security check to enter the building and participate in the meeting. A written

notification is encouraged to make entry through security quicker. To request an escort during the hearing, call Ana Marie Balingit-Wines at 301-443-2030.

2. (Audio Portion) Call the conference phone number 855-303-0062 and provide the following information: Leader's Name: Dr. Narayan Nair, Password: 622245.

3. (Visual Portion) Connect to the NPRM-Public Hearing Adobe Connect Pro Meeting using the following URL: https://hrsa.connectsolutions.com/nprm_public_hearing/ (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL:

https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview. Call (301) 443-2030 or send an email to abalingit-wines@hrsa.gov if you are having trouble connecting to the meeting site.

FOR FURTHER INFORMATION CONTACT: Dr. Narayan Nair, Director, Division of Injury Compensation Programs, at 800-338-2382 or by email: nnair@hrsa.gov.

SUPPLEMENTARY INFORMATION: As required by statute, the Secretary proposes to amend the Vaccine Injury Table (Table) by regulation to include vaccines recommended by the CDC for routine administration in pregnant women. The proposed rule, which was published in the *Federal Register* on April 4, 2018 (83 FR 14391; <https://www.gpo.gov/fdsys/pkg/FR-2018-04-04/pdf/2018-06770.pdf>), would amend the existing language in Item XVII of the Table to include “and/or pregnant women” after “children.” This proposed revision would add to the general category of the Table any new vaccine recommended by the CDC for routine administration in pregnant women after imposition of an excise tax and publication of a notice of

coverage. The Secretary is seeking public comment on the proposed revision to the Table. The public comment period for the NPRM closes on October 1, 2018.

A public hearing on the NPRM will take place on September 17, 2018. This hearing is to provide an open forum for the presentation of information and views concerning the proposed revision to the Table by interested persons. In preparing a final regulation, the Secretary will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the NPRM. The presiding officer, representing the Secretary of HHS, will be Dr. Narayan Nair, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration.

Individuals or representatives of interested organizations may participate in the public hearing in accordance with the following schedule and procedures. Persons who wish to participate should file a notice of participation with the Department of Health and Human Services (HHS) on or before September 3, 2018. The notice should be mailed to the Division of Injury Compensation Programs, Room 08N146B, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mailed to abalingit-wines@hrsa.gov. To ensure timely handling, any outer envelope or the subject line of an e-mail should be clearly marked "VICP NPRM Hearing." The notice of participation should contain the interested person's name, address, e-mail address, telephone number, any business or organizational affiliation of the person desiring to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation. Groups that have similar interests should consolidate their comments as part of one presentation. Time available for the hearing will be allocated among the persons who properly file notices of participation. If time permits, interested parties attending the hearing who did not submit notice

of participation in advance will be allowed to make an oral presentation at the conclusion of the hearing.

Persons who find that there is insufficient time to submit the required information in writing may give oral notice of participation by calling Ana Marie Balingit-Wines, Division of Injury Compensation Programs, at (301) 443-2030, no later than September 3, 2018. After reviewing the notices of participation and accompanying information, HHS will schedule each appearance and notify each participant by mail, e-mail, or telephone of the time allotted to the person(s) and the approximate time the person's oral presentation is scheduled to begin.

Written comments and transcripts of the hearing will be made available for public inspection as soon as they have been prepared, on weekdays (except Federal holidays) between the hours of 8:30 a.m. and 5:00 p.m. (EDT) at the Division of Injury Compensation Programs, Room 08N146B, 5600 Fishers Lane, Rockville, Maryland 20857.

Dated: August 24, 2018.

Alex M. Azar II

Secretary,

Department of Health and Human Services.

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